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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,412	07/23/2004	Takashi Yasukochi	KUZ-0018	3951
7590 Jane Massey Licata Licata & Tyrrell 66 East Main Street Marlton, NJ 08053			EXAMINER CHEUNG, WILLIAM K	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 04/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/502,412

Applicant(s)

YASUKOCHI ET AL.

Examiner

WILLIAM K. CHEUNG

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 7, 10-12, 16-19, 21-23 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 10-12, 16-19, 21-23 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 111507
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. In view of the amendment filed January 24, 2008, claims 1-4, 6, 8, 9, 13-15, 20, 24-26 have been cancelled and new claim 29 has been added. Claims 5, 7, 10-12, 16-19, 21-23, 27-29.
2. In view of the amendment filed January 24, 2008, the rejection of 19 is rejected under 35 U.S.C. 112, second paragraph, is withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 5, 7, 10-12, 16-19, 21-23, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiyama (WO 99/02141) in view of Matsumoto et al. (US

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5,532,373), for the reasons adequately set forth from paragraph 8 of the office action of October 24, 2007.

Claim 27 (currently amended): A process for the production of a medical patch, said process comprising:

- (a) dissolving in a lower alcohol:
 - (i) a hormonal drug selected from estradiol and norethisterone acetate; and
 - (ii) an acrylic polymer or a methacrylic polymer having at least one hydroxyl or carboxyl group in a crosslinkable monomer unit;
- (b) adding to the solution of step (a) one or more crosslinking agents selected from the group consisting of metal alcohollates, boric acid, borate and borate ester;
- (c) spreading the mixture of step (b) on a film; and
- (d) thermally crosslinking the polymer of (ii) with the one or more crosslinking agents of step (b) either simultaneously with or followed by laminating to a support, ~~collectively thereby to form the medical patch.~~

Claim 28 (currently amended): A process for the production of a medical patch, said process comprising:

- (a) dissolving in a lower alcohol:
 - (i) a drug selected from estradiol and norethisterone acetate; and
 - (ii) one or more crosslinking agents selected from the group consisting of metal alcohollates, boric acid, borate and borate ester;
- (b) adding to the solution of step (a) an acrylic polymer or a methacrylic polymer having at least one hydroxyl or carboxyl group in a crosslinkable monomer unit to the solution;
- (c) spreading the mixture of step (b) on a film; and
- (d) thermally crosslinking the polymer of step (b) with the one or more crosslinking agents of (ii) either simultaneously with or followed by laminating to a support, ~~collectively thereby to form the medical patch.~~

Kamiyama (abstract) discloses a process for preparing transdermal patches comprising an adhesive. Kamiyama (page 5, line 20-28) discloses that the preparation of the adhesive compositions mixing acrylic based materials and polar monomers such

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as hydroxyethyl acrylate (typically is referred as 2-hydroxyethylacrylate) and hydroxypropyl acrylate (typically is referred as 3-hydroxypropyl acrylate), and vinyl pyrrolidone to enhance drug solubility of drugs (page 6, line 1-6), such as oestradiol and norethisterone (page 13, line 3-4).

Regarding the claimed "spreading the mixture on a film", Kamiyama (page 14, example 1) clearly discloses preparing the adhesive composition comprising the drugs by mixing, and applied to a backing film, and the film is allowed to dry. The disclosed drying step also indicates that the prepared adhesive film product is substantially free of water. Further, the mixing step teachings of Kamiyama also encompass the addition of the ingredients in all possible orders or sequences, which include the adding sequence of claims 27 and 28.

Regarding the new claim 29, Kamiyama (page 2, line 3; page 27, claims 11, 16) clearly teach a process comprising the use of N-vinyl pyrrolidone (or vinyl pyrrolidone).

The difference between the invention of claims 5, 7, 10-12, 16-19, 21-23, 27-29 and Kamiyama is that Kamiyama employs peroxide as curing agent, while the claimed invention involves the use of boric acid.

Matsumoto et al. (col. 1, line 12-33) disclose a process for preparing a photopolymerizable composition for producing lithographic sheets or films, resin reliefs, resists or photomasks or printed circuit board manufacture, black and white or color transfer development sheets of development sheets. Matsumoto et al. (col. 29, 23-38) clearly disclose that the adhesive having a film backing is capable of releasing its content (a dye or a drug). Further, Matsumoto et al. (col. 27, line 65-67) disclose that

the composition comprises polyols, a lower alcohol (col. 29, line 21; col. 38, line 10-13), and crosslinking agent such as boric acid (col. 36, line 4). In view of such disclosure, it would not be difficult to one of ordinary skill in art that the material compositions of Matsumoto et al. and Kamiyama are very similar, particularly relating to the use of adhesive film for release a substance. Therefore, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-19, 21-23, 27-29.

Response to Arguments

5. Applicant's arguments filed January 24, 2008 have been fully considered but they are not persuasive.

Applicants argue the Kamiyama and Matsumoto et al. are too far removed from the knowledge of one of ordinary skill in art, and too lacking in the design incentives, to be combined. However, the examiner disagrees because, based on material composition, both Kamiyama and Matsumoto et al. are drawn to substantially identical acrylic based adhesive, film backing and chemical release mechanism for releasing a chemical, drug, or a dye. The mere difference in the intended end use would not deter one of ordinary skill in art from combining the teachings of Kamiyama and Matsumoto et

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al. Rather, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-19, 21-23, 27-29.

Regarding claim 27, applicants argue that Kamiyama fails to teach dissolution of a drug and a polymer in a lower alcohol solution before adding a crosslinking agent. Regarding the mixing sequence, applicants must recognize that Kamiyama (page 14, example 1) clearly discloses preparing the adhesive composition comprising the drugs by mixing, and applied to a backing film, and the film is allowed to dry. The disclosed drying step also indicates that the prepared adhesive film product is substantially free of water. Further, the mixing step teachings of Kamiyama also encompass the addition of the ingredients in all possible orders or sequences, which include the adding sequence of claims 27. Although peroxide is added in the initial step, applicants argue that Kamiyama does not recite the addition of any crosslinker after the drug and polymer have been dissolved in an alcohol. Applicants must recognize that Matsumoto et al. (col. 27, line 65-67) disclose that the composition comprises polyols, a lower alcohol (col. 29, line 21; col. 38, line 10-13), and crosslinking agent such as boric acid (col. 36, line 4). In view of such disclosure, it would not be difficult to one of ordinary skill in art that the material compositions of Matsumoto et al. and Kamiyama are very similar,

particularly relating to the use of adhesive film for release a substance. Therefore, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-19, 21-23, 27-29. Applicants must also recognize that Kamiyama (page 15, line 3-4) clearly teach that methanol (a lower alcohol) can be used to dissolve drugs. In view of the substantially identical acrylic type polymer disclosed in Kamiyama and as claimed, there is no reason for the examiner that the polymers of Kamiyama can not be dissolved in the lower alcohol of Kamiyama. Regarding applicants' argument that Kamiyama involves using toluene ... and ethyl acetate in page 21 of Kamiyama, applicants must recognize that the claims as written "comprising" do not exclude the use of mixed solvent system comprising toluene ... and ethylacetate.

Regarding applicants' argument that the broad interpretation of "dissolving" does not include mixing or adding, the examiner disagrees because one of ordinary skill in art would have recognized that without bringing a solute and solvent together by mixing or by adding, it would be difficult to dissolve a solute into a solvent.

Regarding applicants' argument that Matsumoto fails to dissolve a drug and a polymer in lower alcohol, applicants must recognize that such teachings have already been taught by Kamiyama. Regarding applicants' argument that Matsumoto never add

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boric acid to a polymer/drug solution, applicants must recognize that when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-19, 21-23, 27-29. Therefore, the examiner has a reasonable basis that the combined teachings of the Kamiyama and Matsumoto et al. would result in dissolving a drug and a polymer in solvent system comprising a lower alcohol. Although the process of Matsumoto et al. involves micro-encapsulation, the micro-encapsulation process is not adequate to prevent the boric acid teaching of Matsumoto to be incorporated into Kamiyama.

Regarding applicants' argument that the microcapsules typical to Matsumoto are very specific sizes and preferably respond to changes due to pressure under 10kg/cm², applicants must recognize that the argument is not supported by the claims as written. Applicants must recognize that the recited "medical patches" means a film/adhesive comprising a drug. Therefore, since both the films of Kamiyama and matsumoto are structurally capable of functioning as a medical patch, the rejection set forth is proper. Applicants must recognize that even a medical patch can have other intended uses. And for the same reasons, the film patches as taught in Matsumoto can also be used as medical patches.

Regarding applicants' argument that Matsumoto also teaches other photosensitive components that are related to medical patch application, applicants must recognize that such argument would not prevent the boric acid from being incorporated into Kamiyama because nothing in the claims indicate that the invention as claimed can not be photosensitive.

Regarding applicants' argument that the working examples in Matsumoto do not involve using boric acid, applicants must recognize that the teachings of a prior art is not limited to its working example or preferable embodiments.

In view of the reasons set forth above, the rejection set forth is proper.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William K. Cheung whose telephone number is (571) 272-1097. The examiner can normally be reached on Monday-Friday 9:00AM to 2:00PM; 4:00PM to 8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David WU can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/William K Cheung/
Primary Examiner, Art Unit 1796

William K. Cheung, Ph. D.

Primary Examiner

April 25, 2008

